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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,447	01/22/2002	James R. Keogh	P-9170.00	5485

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,447

Applicant(s)

KEOGH ET AL.

Examiner

Casey Hagopian

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9, 10, 233, 273-276, 278, 280 and 281 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 277 and 279 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-10,52-61,103-114,162-173,233-243,246-249,255-261,264-267 and 273-292.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 52-61,103-114,162-173,234-243,246-249,255-261,264-267 and 282-292.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-10, 233 and 273-281) in the reply filed on 5/10/2006 is acknowledged. The traversal is on the ground(s) that the examiner has allegedly not demonstrated a serious search burden. This is not found persuasive because the different inventions contain different method steps, which impart a different scope and thus a different search strategy. To illustrate, claim 1 is drawn to a method comprising coating a medical device with a hydrophilic polymer comprising a guanidino moiety; claim 52 is drawn to a method comprising coating a medical device with a hydrophilic polymer comprising a catechol moiety, 103 is drawn to a method comprising coating a medical device with a biomolecule comprising a guanidino moiety and claim 162 is drawn to a method comprising a medical device with a biomolecule comprising a catechol moiety. Catechols and guanidines are unrelated compounds and as such one would not be found obvious over the other. Similarly, biomolecules, including various pharmaceuticals, and hydrophilic polymers are unrelated; one would not be found obvious over the other. Subsequently, the unrelated subject matter requires very different search strategies and thus, a search burden is present. For these reasons, the requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

2. Applicants arguments are persuasive, thus all previous rejections are hereby withdrawn. However, upon further consideration, a new ground(s) of rejection is made (see *New Rejections* section of the Office Action).

NEW REJECTIONS

Claim Rejections - 35 USC § 112, 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 and its depending claims 2-10, 276, 280 and 281 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 contains the method step of coating the medical device with a hydrophilic polymer. It is unclear as to when the catechol is disposed on the surface of the device, when the chemical bond is formed and whether the catechol is disposed on the surface of the device separately from the hydrophilic polymer or if it is included in for instance, a composition comprising the hydrophilic polymer and guanidino moiety and then disposed on the surface of the device. Appropriate clarification/correction is respectfully requested.

6. Claims 5 and 276 contain a Markush group for the hydrophilic polymer of claims 1 and 233, respectively, however one the species is "a polymer comprising a hydrophilic

Art Unit: 1615

chemical moiety". It is unclear as to how said limitation is further limiting of a "hydrophilic polymer" as all "hydrophilic polymers" comprise a "hydrophilic chemical moiety". Appropriate clarification/correction is respectfully requested.

7. As discussed above, it is unclear in claim 1 whether the catechol is disposed onto the surface of the medical device separately from the hydrophilic polymer because the claim lacks a method step that clearly point out when the catechol is disposed onto the surface. Accordingly, claims 9, 10, 280 and 281 complicate the issue further. If claims 1 and 233 intend for a catechol to be disposed onto the surface prior to the application of the hydrophilic polymer, then claims 9, 10, 280 and 281 do not appear to further limit the claim. Appropriate correction/clarification is respectfully requested.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5, 7, 9, 10, 233, 273-276, 278, 280 and 281 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawhney (USPN 6,818,018 B1). In light of broadly written claim 1 and the rejection under 35 USC 112, 2nd paragraph the examiner is giving the claims the broadest reasonable interpretation. As such, the examiner is interpreting claim 1 in such a way that allows for a composition comprising a catechol and a hydrophilic polymer containing a guanidino moiety that is coated on a medical

Art Unit: 1615

device. Inherently, said composition would dispose a catechol on the surface of the device and a chemical bond would form between the catechol and guanidino moiety. With that in mind, Sawhney discloses compositions and methods for forming hydrogels for the use of medical device coatings (abstract). More specifically, Sawhney discloses that the compositions include preferred water-soluble polymers including polyguanidine (column 12, lines 18-21) and bioactive species including the specific catechol, dopamine (column 17, line 46). Sawhney also discloses that the bioactive can be contained in a secondary coating (column 16, lines 2-4). Sawhney further discloses particular medical devices, including catheters, cannulas, bone prostheses, minipumps, platinum wires and so on (column 18, lines 26-36). Sawhney also contemplates primers, for example, to establish a mechanical or chemical linkage with the underlying surface (column 22, lines 22-30). Thus, the disclosures of Sawhney render the instant claims anticipated.

Claim Objections

10. Claims 6, 8, 277 and 279 are objected to as being dependent upon a rejected base claim.

Conclusion

11. Claims 1-5, 7, 9-10, 233, 273-276, 278 and 280-281 have been rejected and claims 6, 8, 277 and 279 have been objected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

Carlos A. Azpuru
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GROUP 1500